September 16, 2021

Medtronic Neurosurgery
Sudeep Nambiar
Regulatory Affairs Manager
5290 California Avenue
Irvine, California 92617

Re: K212641
Trade/Device Name: StrataMR II Valves and Shunts
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: August 17, 2021
Received: August 20, 2021

Dear Sudeep Nambiar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce -S

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212641

Device Name
StrataMR II Valves and Shunts

Indications for Use *(Describe)*
The StrataMR II Valves and shunts are designed to provide continuous Cerebrospinal Fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The design enables the physician to non-invasively adjust valve pressure/performance level pre-and post-implantation by using magnetic adjustment tools without the need of radiographic confirmation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. Company: Medtronic, Inc.
Medtronic Neurosurgery
5290 California Ave
Irvine, California 92617 USA

Contact: Swara Vashi
Regulatory Affairs Specialist
swara.vashi@medtronic.com
Telephone Number: 267-638-8778

Alternate Contact: Sudeep Nambiar
Regulatory Affairs Manager
sudeep.nambiar@medtronic.com
Telephone Number: 607-349-9048

Date of Summary Prepared: 19 August 2021

II. Proprietary Trade Name: StrataMR™ II Valves and Shunts

III. Regulatory Class: II

IV. Primary Classification:
Name: Central nervous system fluid shunt and components
Product Code: JXG
Regulation: 882.5550

V. Product Description
The StrataMR™ II adjustable valves are single-use implantable devices which provide a non-invasive method to address changing patient needs in the management of hydrocephalus. The valves and their associated catheters drain cerebrospinal fluid (CSF) from ventricles in the brain into the peritoneal cavity or the right atrium of the heart, where it is absorbed by the body. StrataMR™ II valve incorporates a ball and cone pressure valve in series with a normally closed siphon control mechanism. Flow control is achieved, and retrograde flow is prevented by combined resistance of the ball and cone and siphon control diaphragm. Pre- and post-implantation, the performance level of the valve can be modified by StrataMR™ Adjustment Tools: Locator tool, guider tool, indicator tool and adjustment tool cleared under K181622.

VI. Indications for Use
The StrataMR™ II Valves and shunts are designed to provide continuous Cerebrospinal Fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The design enables the physician to non-invasively adjust valve pressure/performance level pre-and post-implantation by using magnetic adjustment tools without the need of radiographic confirmation.

VII. Summary of the Technological Characteristics

The subject device and the predicate device have the same indications for use, intended use, fundamental technology and operating principle. The primary difference between the subject device StrataMR™ II and the predicate StrataMR™ is in the cap material. The cap material of the subject device StrataMR™ II is same as the reference device, Strata™ II that was cleared under K042465 and K060681. An additional tantalum marker has been included on the valves to noninvasively differentiate between the subject StrataMR™ II and predicate StrataMR™ valves. Outer sterile packaging barrier is changed from Mylar to Nylon with Tyvek.

VIII. Identification of Legally Marketed Predicate Devices

Primary Predicate device: StrataMR™ Valves and Shunts Medtronic (K152700)
Reference Predicate: Strata™ II Valve and Shunt (K060681)

IX. Device Comparison

The tables below provide a summary of the device

Characteristic		Subject Device	Predicate Device	Reference Predicate Device
Device Name		StrataMR™ II Valves and Shunts	StrataMR™ Valves and Shunts	Strata™ II Valves and Shunts
510k Number		K212641	K152700	K060681
Indications for Use		The StrataMR™ II valves and shunts are designed to provide continuous cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The design enables the physician to non-invasively adjust valve pressure/performance level pre-and post-implantation by using magnetic adjustment tools without the need for radiographic confirmation.	The Medtronic StrataMR™ valves and shunts are designed to provide continuous cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The design enables the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using magnetic adjustment tools without the need for radiographic information.	The Medtronic PS Medical Strata™ II Valve and Shunt Assemblies with and without BioGlide are shunt components designed to provide continued CSF flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The design allows the physician to non-invasively adjust valve pressure/performance level pre-and post-implantation tool without the need for radiographic confirmation.
Physical Characteristics/ Principal of operation				
Dimension	**Maximum Length**	Small: 1.93”	Small: 1.93”	Small: 1.89”
		Regular: 2.29”	Regular: 2.29”	Regular: 2.25”
	Maximum Height	Small: 0.37”	Small: 0.35”	Small: 0.30”
		Regular :0.42”	Regular :0.40”	Regular :0.35”
	Maximum Width	Small: 0.59”	Small: 0.59”	Small: 0.53”
		Regular: 0.70”	Regular: 0.70”	Regular: 0.67”
Pressure settings		5 discrete pressure settings	Same	Same

Characteristic	Subject Device	Predicate Device	Reference Predicate Device
Adjustment Tools	Adjustment tool set contains locator tool, indicator tool, adjustment tool and guider tool cleared under K181622 and K152700	Same	Strata™ II adjustment kit contains locator tool, indicator tool and Adjustment tool cleared under K060681
Shunt system components	Valves used with existing, legally marketed shunt components and accessories	Same	Same
Patient contact and duration	Tissue/bone contact with long term duration (>30 days)	Same	Same
Shelf Life	22 months	3 years	3 years
Sterilization Method	Ethylene Oxide	Same	Same
Packaging material	Valves and shunts are packaged in plastic tray sealed with Tyvek lid. Sealed tray is placed in a Tyvek-Nylon peel pouch which is then placed in carton.	Valves and shunts are packaged in plastic tray sealed with Tyvek lid. Sealed tray is placed in a Tyvek-Mylar peel pouch (StrataMR valves model no. 42955 & 42965) or Tyvek-Nylon pouch (StrataMR shunt assembly model no. 46955 & 46965) which is then placed in carton.	Valves and shunts are packaged in plastic tray sealed with Tyvek lid. Sealed tray is placed in a Tyvek-Nylon peel pouch which is then placed in carton.

X. Discussion of the Performance testing

Performance Data – Bench

Test	Test Summary	Results
Resistance to Leakage	Resistance to leakage was measured using air. The valves were required to show no leakage for 5 minutes with a differential pressure from inside to outside of 1 m H_20.	All valves met acceptance criteria, demonstrating that there are no concerns regarding valve integrity/leakage relative to the predicate device.
Reservoir dome needle puncture	Reservoir domes were required to show no leakage when repeatedly punctured with a non-coring needle under pressure.	

Test	Test Summary	Results
Dynamic Breaking Strength	Tension was applied in the flow direction, leading to an elongation of the shunt of 10% or a maximum force of 5 N. Shunts were required to exhibit no break, rupture or disconnection after 100,000 cycles at frequency 1.0 ± 0.2 Hz.	
Opening Pressure	The test demonstrates valve flow following valve manufacture, the valve was to show patency at a pressure that meets manufacturer's specifications	All valves met acceptance criteria, demonstrating that there are no concerns regarding valve opening pressure (patency).
Pressure/Flow	Pressure/flow performance was tested in accordance to BS EN ISO 7197:2009. The measured pressure has to remain inside the manufacturer's specifications	All valves met acceptance criteria, demonstrating that there are no concerns regarding pressure/flow performance relative to the predicate device.
Posture Effect	The test compared valve pressure at -50 cm hydrostatic pressure with valve pressure at 0 cm hydrostatic pressure. The difference was required to meet manufacturer's specifications	
Ability to withstand Overpressure	After application of positive pressure of 1 m water to the open shunt in accordance with BS EN ISO 7197:2009, valves were required to meet pre-established pressure/flow specifications.	
Bursting Pressure	After application of positive pressure of 2 m water in accordance with BS EN ISO 7197:2009, valves were required to meet pre-established pressure/flow specifications.	
Long Term Stability	Valves were placed in a water bath with temperature of 37°C ± 5° while pumping water through the valves at an average flow rate of 20 mL/h for 28 days. During this time, valves were required to maintain pre-established pressure/flow specifications.	
Flushing capacity	Flushing volume that is produced from valve reservoir compressions was tested.	All valves met acceptance criteria, demonstrating that there are no concerns regarding reservoir volume relative to the predicate device.
Identification of shunts *in vivo*	Valves underwent X-ray imaging. The valve identification markers must be visible, and the valve setting must be readable in the X-ray images.	All valves met acceptance criteria, demonstrating that there are no concerns regarding identification of the valve via X-ray relative to the predicate device.

Test	Test Summary	Results
Post-MRI Functional Testing	Valves were exposed to multiple MRI exposures in clinically relevant orientations. After MRI exposure, valves were required to: (1) maintain the pre-conditioning pressure setting, (2) be able to be read and adjusted, and (3) meet pre-established pressure/flow specifications.	All valves met acceptance criteria, demonstrating that there are no concerns regarding performance after MRI exposure relative to the predicate device.
MRI Safety Information	• Magnetically induced displacement force testing per ASTM F2052-15 • Magnetically induced torque testing per ASTM F2213-06 • Radio Frequency induced heating testing per ASTM F2182-11a • Image artifact testing per ASTM F2119-07	Test results demonstrated that StrataMR ™ II valves are MR conditional and that there are not MRI safety concerns relative to the predicate device when scanned according to the MR conditions specified in the labeling.

StrataMR™ II valves and shunts met applicable pre-established acceptance criteria and raised no concerns regarding safety and effectiveness relative to the predicate device. Therefore, bench testing summarized above supports the substantial equivalence of StrataMR™ II and the predicate.

Biocompatibility Testing

The following Biocompatibility tests were conducted per ISO 10993-1 endpoints for tissue/bone/CSF implant device with long-term contact.

Test	Test Method Summary	Results
Cytotoxicity- MEM Elution	Cell culture treated with test sample exhibited no signs of toxicity (Grade 0)	Non-cytotoxic
Irritation-Intracutaneous study in rabbits	Animals treated with test sample exhibited no dermal reactions (Grade 0)	Non-irritant
Sensitization- Guinea Pig Maximization	Animals treated with test sample exhibited no dermal reactions.	Non-sensitizer
Systemic toxicity – Acute systemic toxicity study in mice	Animals treated with test sample exhibited no mortality or evidence of systemic toxicity	Non-toxic
Material Mediated Pyrogenicity- USP Rabbit Pyrogen Study	Individual animals treated with test sample exhibited no temperature rise above 0.5°C	Non-pyrogenic
Genotoxicity/ Carcinogenicity	The test article did not show a significantly greater biological reaction than the controls	Non-mutagenic
Implantation	The test did not show a significantly greater biological reaction than the	Non-toxic

Test	Test Method Summary	Results
	control (Grade 0 - no reaction)	
Hemocompatibility	The test article exhibited no hemolysis and was within the control values	Non-hemolytic

StrataMR™ II valves and shunts passed biocompatibility testing demonstrating that StrataMR™ II material change does not raise biocompatibility concerns relative to predicate device. Therefore, biocompatibility testing summarized above supports the substantial equivalence of StrataMR™ II to the predicate device.

Performance Data – Animal
No animal testing was conducted. The differences in technological characteristics do not raise new questions of safety and effectiveness as demonstrated through non-clinical bench testing using well established acceptable scientific methods.

Performance Data – Clinical
No clinical testing was conducted. The differences in technological characteristics do not raise new questions of safety and effectiveness as demonstrated through non-clinical bench testing using well established acceptable scientific methods.

XI. Conclusion

Based on indications for use, design, technological characteristics, and performance testing conducted on the proposed device, it can be concluded that the StrataMR™ II valves and Shunts are substantially equivalent to StrataMR™ valves and Shunts cleared under K152700.